



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0600]

Health Document Submission Requirements for Tobacco Products; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a revised draft guidance for industry entitled "Health Document Submission Requirements for Tobacco Products." The revised draft guidance is intended to assist persons making certain document submissions to FDA as required by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this revised draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2009-D-0600 for "Health Document Submission Requirements for Tobacco Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions,"

publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:  
<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the revised draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000. Send two self-addressed adhesive labels to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Katherine Collins, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000, 1-877-287-1373, email: AskCTP@fda.hhs.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

We are announcing the availability of a revised draft guidance for industry entitled "Health Document Submission Requirements for Tobacco Products." We are issuing this draft guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). The draft guidance, when finalized, is intended to assist persons making certain document submissions to FDA as required by the Tobacco Control Act.

The Tobacco Control Act, enacted on June 22, 2009, amends the FD&C Act and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public's health (Pub. L. 111-31). Among other things, the Tobacco Control Act adds section 904(a)(4) to the FD&C Act (21 U.S.C. 387d(a)(4)), requiring each tobacco product manufacturer or importer, or agents thereof to submit all documents developed

after June 22, 2009, that relate to any "health, toxicological, behavioral, or physiological effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives."

The revised draft guidance includes guidance for manufacturers or importers of products that are newly deemed as tobacco products that are subject to Chapter IX of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately subject to the tobacco provisions of the FD&C Act, including section 904(a)(4), and to FDA's regulatory authority. As for other types of tobacco products, section 901(b) of the FD&C Act (21 U.S.C. 387a) grants FDA authority to deem those products subject to the law as well. Pursuant to that authority, FDA issued a rule deeming all other products that meet the statutory definition of "tobacco product", set forth in section 201(rr) of the FD&C Act, except for accessories of those products, as subject to the FD&C Act (81 FR 28974). FDA published the final rule on May 10, 2016 (81 FR 28974), and it became effective on August 8, 2016. Manufacturers and importers of tobacco products that have been deemed subject to the FD&C Act are now required to comply with Chapter IX of the FD&C Act, including section 904(a)(4).

## II. Significance of Guidance

FDA is issuing this revised draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, represents the current thinking of FDA on health document submission requirements. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

### III. Paperwork Reduction Act of 1995

This revised draft guidance also refers to previously approved collections of information found in FDA statute. The revised draft guidance includes information and recommendations for how to provide health document submissions. The collections of information in section 904(a)(4) of the FD&C Act have been approved under OMB control number 0910-0654.

### IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the draft guidance at either <http://www.regulations.gov> or

<http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: August 31, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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